

Docket No. 12013/58201

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No. : 09/883,178

Applicant : Wendy Naimark, *et al.*

Title : METHOD AND APPARATUS TO MODIFY A FLUID USING A
SELECTIVELY PERMEABLE MEMBRANE

Filed : June 19, 2001

TC/A.U. : 3767

Examiner : Elizabeth MacNeill

Customer No. : 23838

COMMISSIONER FOR PATENTS
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PRE-APPEAL BRIEF REQUEST FOR REVIEW

Sir:

The Applicant respectfully requests pre-appeal review of this application for the following reasons.

The Advisory Action dated May 5, 2008, indicated that upon appeal, the proposed amendment filed April 17, 2008, would be entered. Accordingly, these remarks are directed to the claims after entry of that amendment. After entry of that amendment, claims 13-18 and 24-30 are pending. Claims 13, 18 and 28 are independent.

Rejections of Prior Claims 31-33 (now incorporated into claims 13, 18 & 28)

Claims 31-33 (among others) were rejected under 35 U.S.C. § 103(a), with the Office Action relying on U.S. Patent No. 5,833,652 to Preissman ("Preissman") in view of U.S. Patent No. 4,552,555 to Theeuwes ("Theeuwes").

Applicant's Invention and Example Embodiments

Applicant's invention as previously claimed in claims 31-33 and now claimed in claims 13, 18 and 28 is directed to a device for modifying a fluid moving through a vessel prior to the ejection of the fluid from the vessel into the body of a patient. In these claims, the vessel has a

selectively permeable membrane that is “adapted to extract a compound from fluid in the [mixing or fluid modification] chamber.” An example of an embodiment within the scope of at least independent claims 13, 18 and 28 is illustrated in Applicant’s Figure 1, reproduced below:

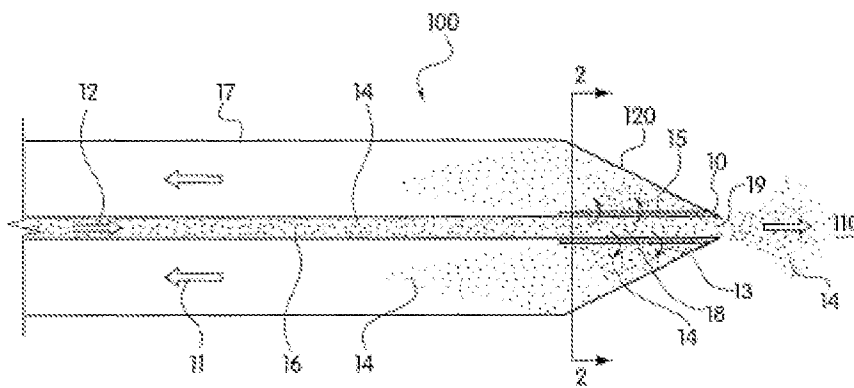


FIG. 1

In this embodiment, the vessel is a catheter 100 comprising a first lumen 16, a second lumen 17, and an exit orifice 19 located at a distal end of the first lumen. A mixing or modification chamber 18 is positioned within the first lumen 16 proximal to the exit orifice 19. The arrows 13 show the flow of compounds through a selectively permeable membrane 15 in a passageway located proximal to the exit orifice 19, the passageway being positioned between the chamber 18 and the second lumen 17. The passageway fluidly connects the chamber 18 to the second lumen 17, and the selectively permeable membrane 15 is positioned to selectively pass compounds through the passageway between the chamber 18 and the second lumen 17.

As an example of a use of this embodiment, fluid including a therapeutic agent and a solvent may be transported through the first lumen 16 from a proximal end of the catheter 100 to a distal end of the catheter 100. Before reaching the exit orifice 19, the fluid passes into the fluid mixing or modification chamber 18 located within the first lumen 16. Because the solvent of the fluid is able to pass through the selectively permeable membrane 15, solvent is drawn away from the fluid in the chamber 18 and into the second lumen 17. Thus, the amount of solvent in the fluid is lowered prior to delivery of the fluid through the exit orifice 19 to the patient. Thus, as claimed, the selectively permeable membrane is “adapted to extract a compound from fluid in the [mixing or fluid modification] chamber.”

The Priessman Patent

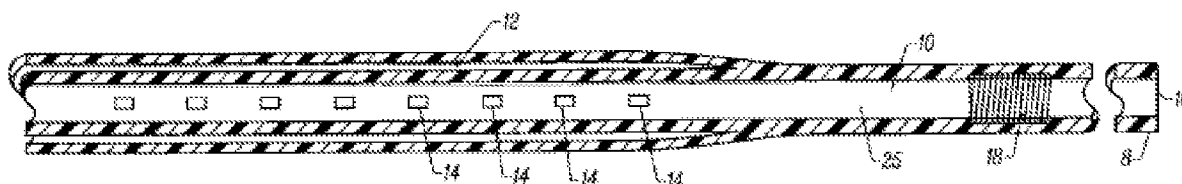
The Priessman reference is directed to a mixing catheter that has a first lumen 10 and a second lumen 12 that are connected together at connecting passages 14. According to

Priessman, “This arrangement permits the two components passing through the first and second lumens 10 and 12 to mix within first lumen 10 prior to exiting an exterior opening 16 formed at distal end 8.” (col. 2, lines 45-48 (emphasis added)).

The Priessman reference is explicitly directed to mixing two components from the two lumens. Its stated purpose is to combine the materials from the two lumens, as opposed to extracting, filtering or separating them.

The Office Action points to the Theeuwes reference for a permeable membrane to add to the Priessman device. The Office Action states that it would have been obvious to add such a membrane in order to “prevent bacteria from harming the patient or prevent an overdose or under dose from being administered.” (Office Action, page 3). While the Applicant respectfully disagrees with the combination for the reasons previously stated, the Applicant nevertheless respectfully submits that even if the combination as proposed in the Office Action were made, it would still not meet the invention as now claimed in Applicant’s independent claims, for the following reasons.

Figure 2 of Priessman, relied on in the Office Action, is shown below:



The Priessman reference describes the device as follows:

Catheter shaft 4 is a dual lumen, coaxial catheter shaft including a first, inner lumen 10 and a second, external lumen 12. External lumen 12 terminates about 1-10 cm from distal end 8. Lumens 10, 12 are fluidly coupled through a number of connecting passages 14. This arrangement permits the two components passing through first and second lumens 10, 12 to mix within first lumen 10 prior to exiting an exterior opening 16 formed at distal end 8. ...

* * *

... Once properly located at the target site, ... first and second components can be directed through [first] and second lumens 10, 12 for mixing within mixing region 25 of first lumen 10. Use of mixing catheter 2 permits two different components to be mixed just prior to delivery to the target site through external opening 16 for maximum therapeutic effect ...

(col. 2, line 40 – col. 3, line 7).

The Office Action states that Applicant's claimed mixing chamber is met by Priessman's "area [of first lumen 10] with holes 14." The Office Action further states that Applicant's claimed passageways are met by the holes 14 themselves. The Office Action then proposes putting membranes in the holes 14.

Even if this modification could be made to the Priessman device, it would still not meet Applicant's claims. Applicant's claims require that the selectively permeable membrane is "adapted to extract a compound from fluid in the mixing chamber [or fluid modification chamber]." Even if a membrane were put in the holes 14 of Priessman, it would not be "adapted to extract" a compound from fluid in what the Office Action calls the mixing chamber, i.e., the area of the first lumen 10 adjacent the holes 14. This is because, unlike Applicant's claimed invention, Priessman is not designed to extract anything from the first lumen. Rather, Priessman is designed to combine the fluid from lumen 12 into the fluid in lumen 10 "for mixing within mixing region 25 of first lumen 10." According to the Priessman reference itself, "Use of mixing catheter 2 permits two different components to be mixed just prior to delivery to the target site through external opening 16." Thus, Priessman is directed to adding fluid from lumen 12 through the holes 14 and into the mixing region 25 of first lumen 10, and in no way suggest the extraction of compounds from the mixing region 25 or any other region of the lumen 10. Accordingly, Priessman does not disclose or suggest a selectively permeable membrane that is "adapted to extract a compound from fluid in the [mixing or fluid modification] chamber," as recited in Applicant's independent claims.

Moreover, nothing in the prior art suggests modifying the Priessman reference to meet Applicant's claims. In Priessman, there is simply no reason why one would add a membrane for the purpose of extracting a compound from the first lumen 10 into the second lumen 12 through the connecting passages 14, nor any teaching as to how such a modification could be accomplished. Even if the Priessman device could somehow be modified for extracting a compound from the first lumen, that would be directly contrary to the stated objective of Priessman, because it would result in that compound not being delivered to the patient. The stated objective of Priessman is to have the components from the first and second lumens "mixed" and then to have the combined mixture "applied to the target site" of a patient. (col. 1, lines 42-45). Accordingly, there is no suggestion for using a membrane to "extract" a

component from the first lumen of Priessman, and such a modification would be contrary to the Priessman reference itself.

Response to Advisory Action Dated May 5, 2008

In the Advisory Action dated May 5, 2008, the Examiner states:

Theeuwes teaches the use of a bacterial filter in a MIXING catheter. A bacterial filter is beneficial for obvious reasons, such as sterility. Therefore the combination of Priessman in view of Theeuwes would have been obvious to one of ordinary skill in the art to remove bacteria from the solutions which are to be mixed prior to delivery to the patient.

Advisory Action, May 5, 2008, page 2.

Respectfully, this misses the point. Even if one were to accept this argument and place the membrane of Theeuwes in the holes 14 of Priessman as proposed by the Examiner, that would still not meet Applicant's claims. Applicant's claims require that the selectively permeable membrane is "adapted to extract a compound **from** fluid in the mixing chamber [or fluid modification chamber]" (emphasis added). Even if a membrane were put in the holes 14 of Priessman, it would not be "adapted to extract" a compound **from** fluid in what the Office Action calls the mixing chamber in Priessman, i.e., the area of the first lumen 10 adjacent the holes 14. This is because Priessman is designed to combine the fluid from lumen 12 into the fluid in lumen 10, and in no way suggests extracting anything **from** lumen 10 into lumen 12.

CONCLUSION

For the foregoing reasons, the Applicant respectfully requests reconsideration of this application. While no fees are believed to be due, the Office is authorized to charge any underpayment or credit any overpayment to Kenyon & Kenyon's Deposit Account No. 11-0600.

Respectfully submitted,

Dated: 20 May 2008

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